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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,442	02/06/2004	Stephen Naylor	BG9-007	3617
30407	7590	04/07/2005	EXAMINER	
BOWDITCH & DEWEY, LLP 161 WORCESTER ROAD P.O. BOX 9320 FRAMINGHAM, MA 01701-9320			YU, MELANIE J	
		ART UNIT	PAPER NUMBER	
		1641		

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/773,442	NAYLOR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 February 2005.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.  
 4a) Of the above claim(s) 1-18 and 20-22 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 19 and 23-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 08 November 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of group III, claims 19 and 23-30, in the reply filed on 24 February 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-18 and 20-22 have been withdrawn from consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19 and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of the component "chromatography disk" is vague and indefinite because it is unclear what a chromatography disk encompasses. It is unclear if this component is a cylindrical chromatography column or if it even has the same function as a chromatography column.

Regarding claims 23-30 it is unclear whether the third, fourth, fifth and sixth proteins removed from the sample can be the same protein selected from the recited group or if the third, fourth, fifth and sixth proteins must be different from each other.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 19 and 23-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Pieper et al. (US 2002/0127739).

Pieper et al. teach a device for substantially removing a protein from a sample comprising, in serial fluidic communication, a chromatography column (par. 0012, 0020, 0038) and a chromatography disk (a chromatography disk is considered the same as a cylindrical chromatography column and matrices are within the chromatographic columns; par. 0070).

Regarding claims 23-30, Pieper et al. teach a device for depleting a sample of at least three proteins comprising: a first chromatography column (separate matrices are used for separate receptors, par. 0075; each matrix defines a chromatography column, par. 0096; first chromatography column, par. 0078) functionalized to substantially remove albumin from the sample (goal is to remove most abundant proteins, par. 0083; therefore the first matrix, chromatography column, would remove the most abundant protein, albumin, Table 1); a second chromatography column in serial fluidic communication with the first chromatography column (if matrices carry different binding agents, the matrices are in fluidic communication, par. 0070) and functionalized to substantially remove immunoglobulin G from the sample (according to par. 0083, the second matrix would remove the second most abundant protein, Immunoglobulin G, Table 1); and a first chromatography disk in serial fluidic communication with the second chromatography column (a chromatography disk is considered the same as a cylindrical chromatography column and matrices are within the chromatographic columns; par. 0070; fluidic

communication, par. 0070) and functionalized to substantially remove a third protein from the sample (matrices comprise binding agents for most abundant proteins, par. 0083), wherein a third protein is transferrin (third most abundant protein is transferrin, Table 1). Pieper et al. further teach the device comprising a second, third and fourth chromatography disk (removes up to 12 serum proteins of Table 1, par. 0014; can remove between 5 and 10 proteins, which would require 6 chromatography columns, and encompasses the recited 2 chromatography columns and 4 chromatography disks which are interpreted as circular columns, par. 0084), which respectively remove a fourth, fifth, and sixth protein from the sample (proteins are separated by removing the most abundant, par. 0083, and between 5 and 10 proteins can be depleted, which would encompass removing 6 proteins, par. 0084), wherein the proteins are haptoglobin, alpha-1-antitrypsin and alpha-2-macroglobulin, respectively (the fourth through sixth most abundant proteins are haptoglobin, alpha-1-antitrypsin and alpha-2- macroglobulin, Table 1).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 19 and 23-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 7-12 of copending

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Application No. 09/977,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because the solid phase matrices of claims 1-4 of application '358 are porous according to claim 7 and are affinity columns according to claims 8-12. Therefore, the solid phase matrices can be chromatography columns or disks, which are interpreted as circular chromatography columns, as recited in the instant claims 19 and 23-28. Application '358 teaches, in serial fluidic communication, a first and chromatography column for removing ligands from a sample (claim 1) and a first chromatography disk (claim 2). It would be obvious to remove albumin, immunoglobulin G and transferrin proteins from samples of plasma as the first, second and third ligands because the ligands are taught as proteins in claim 5 of application '358. Application '358 further teaches a second and third chromatography disk for removing a fourth and fifth from the sample (claims 3 and 4). It would have been obvious for the fourth and fifth proteins to be alpha-2- macroglobulin or alpha-1-antitrypsin because these are proteins found in plasma, and the ligands are recited as proteins (claim 5).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Melanie Yu*  
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Art Unit 1641

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02/31/05